

REMARKS

Reconsideration of this application is respectfully requested.

Solely to expedite prosecution, applicants have canceled claims 92-127 and 129-144. No new matter is introduced through this amendment.

Upon amendment, claims 128 and 145 are pending in this application.

Applicants address the rejections of these claims below.

Double Patenting Rejections

Claims 128 and 145 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 69, 70, and 72-86 of Appln. No. 09/658,862. Applicants have canceled claims 69, 70, and 72-86 in Appln. No. 09/658,862. Accordingly, this rejection is moot.

Claims 128 and 145 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,525,243 B1. Solely to expedite allowance of the pending claims, and not in acquiescence to this rejection, applicants will submit a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) when the claims are otherwise indicated to be allowable.

Rejections under 35 U.S.C. § 101

Claims 128 and 145 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The Office contends that the pending claims do not sufficiently distinguish over naturally occurring mammals and "lack evidence of the hand-of-man." (Paper No. 20 at 6.)

Applicants traverse the rejection. Applicants' claims are directed to an adult mammal and its "clone." A "clone" of an adult mammal requires asexual reproduction. See *American Heritage College Dictionary* (third edition) at 263 (defining clone as "an organism descended asexually from a single ancestor, such as a plant produced by layering".) Nature does not make "clones" of adult mammals because mammals do not reproduce asexually in nature. Since applicant's claims require asexual reproduction of a mammal, the hand of man is clearly required for applicants' "clone." Accordingly, applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 145 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time that the application was filed. The Office alleges that the specification never contemplates a pair of non-human animals.

Applicants traverse the rejection. The Office concedes that the "specification discloses non-human mammals as nuclear donors and non-human mammals as the clone of the donors, and contemplates them singularly." (Paper No. 20 at 7-8.) Thus, the Office Action concedes that the specification discloses the claimed adult mammal and the claimed clone, as well as the fundamental relationship between them, namely, that of parent and progeny clone. Yet, despite the disclosure of each of the claimed mammals and the fundamental relationship between them, the Office Action contends that there is no description of these mammals "as a pair" in the specification.

Applicants need not disclose the claimed invention in identical words. *Fujikawa v. Wattanasin*, 39 U.S.P.Q.2d 1895, 1904 (Fed. Cir. 1996). Applicants need only allow the skilled artisan to recognize that applicants invented what is claimed. (*Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1995). Applicants' specification fulfills this requirement.

As the Office concedes, applicants disclose a clone of a mammal and donor animal used to make the clone. The term "clone" implies that a mammal is a copy of some other mammal (the donor). See *American Heritage College Dictionary* (third edition) at 263 (defining clone as "an organism descended asexually from a single ancestor, such as a plant produced by layering".) Thus, this term conveys the concept of a pair of animals, the copy and the parental mammal (the donor). Likewise, the term "nuclear donor" implies that the mammal is used to generate a clone. Once again, this term conveys the concept of a pair of animals, the donor mammal and its clone. Indeed, the pair exists when the clone is born, a fact that the skilled artisan would immediately recognize. Thus, applicants' disclosure of a clone and its parental (donor) mammal, together with the fundamental relationship between them, is sufficient to convey to the skilled artisan that applicants invented the claimed invention. Accordingly, applicants' disclosure fulfills the requirements of 35 U.S.C. § 112, first paragraph, and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 128 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in not containing some term indicating the relationship of the products to

each other. The Office contends that it is not clear how infringement would be apparent.

Applicants traverse the rejection. First, applicants point out that determining infringement is not a factor relevant to the Office's determination of patentability. Second, claim 128 contains a term indicating the relationship of the products to each other, namely, "and." By using this conjunction, applicants have indicated that they are claiming the combination of the two recited elements. Thus, this claim encompasses, for example, making the claimed combination of a parent **and** progeny mammal. Since one mammal (the parent) would previously exist, the generation of a "clone" of the preexisting mammal would make the claimed combination of a parent mammal **and** its progeny clone. Accordingly, applicants respectfully submit that claim 128 is definite, and request withdrawal of the rejection.

Rejections under 35 U.S.C. § 102(b) and/or 103(a)

Claims 128 and 145 were rejected under 35 U.S.C. § 102(b) and/or 103(a) over a publication that teaches a heifer that gave birth to twin calves. (Morris et al., 1993).

The Office contends that the heifer and either of the calves of Morris et al. anticipate a non-human adult mammal from which a somatic cell has been taken and a clone of the adult mammal (claim 128). The Office further alleges that the heifer and either of the calves of Morris et al. anticipate the pair of non-human mammals comprising an adult, parental non-human mammal and its offspring produced by cloning (claim 145).

Alternatively, the Office contends that the heifer and either of the calves of Morris et al. make obvious applicants' claimed non-human mammal and its clone (claim 128) and the claimed pair of non-human mammals (claim 145) because there is allegedly no

patentable distinction between Morris' heifer and calves and applicants' claimed mammals.

Applicants traverse the rejection. The heifer and either of the calves of Morris et al. cannot anticipate applicants' claimed mammals because they are missing a limitation of applicants' claims. Claims 128 and 145 require a "clone" of the adult mammal. The calves of Morris et al. are not "clones" of the heifer of Morris et al. Rather, on page 257, Morris et al. indicates that the "heifers were mated." Thus, the calves of Morris et al. were generated by sexual reproduction and would have received half of their chromosomes from each parent. As a result, the calves of Morris et al. received only half of their chromosomes from the parental heifer. In contrast, the clones of claims 128 and 145 receive **all** of their chromosomes from the claimed parental mammal. This difference distinguishes applicants' "clone" from the calves of Morris et al. Accordingly, the heifer and calves of Morris et al. cannot anticipate claims 128 and 145 and applicants respectfully request withdrawal of the rejection.

The Office cannot simply ignore this distinction based on the premise that applicants' claims are "product-by-process claims." First, applicants' process generates a feature in the resultant mammal that is unique, namely, the resultant mammal receives **all** of its chromosomes from a single parent. Since the process generates this unique feature in the resultant mammal, patentable weight must be given to the process recited in claim 128. (See M.P.E.P. § 2113.) Second, claims 128 and 145 recite a "clone." Claim 145 is not a "product-by-process claim." The Office's equating a "clone" with "a method of making by somatic cell nuclear transfer" (Paper No. 20 at 19) is in error. As discussed above, a clone is "an organism descended asexually from a single

ancestor.” Thus, the term “clone” in claims 128 and 145 does not, by itself, attach any process limitations to these claims, but serves as a structural limitation that distinguishes applicants’ claimed mammals from those of the prior art.

Moreover, the difference between the heifer and either of the calves of Morris et al. and applicants’ claimed mammals cannot be considered obvious. Unlike Morris’ calves and heifer, applicants’ clone has the same set of chromosomes as the claimed parental mammal. This property can only be achieved by asexual reproduction and can hardly be said to be an expected property of a sexually reproduced, progeny mammal and its parent.

Prior to applicants’ invention, a parent and progeny would have been expected to have a different chromosomes. Due to the mechanism of sexual reproduction, the progeny would only inherit one half of its chromosomes from each parent. Thus, the fact that applicants’ progeny clone and its parental mammal **have the same set of chromosomes** is an unexpected property of applicants’ claimed mammals. This unexpected property provides for a patentable distinction between the heifer and either of the calves of Morris et al. and the claimed mammals. Accordingly, claims 128 and 145 cannot be considered obvious over Morris et al. and applicants respectfully request withdrawal of the rejection.

Conclusion

Applicants respectfully submit that this application is now in condition for allowance. If the Examiner believes that issues remain to be addressed before a Notice of Allowance, applicants respectfully request that the Examiner contact the undersigned to discuss any outstanding issues.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

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